

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO:
ETHICON WAVE 1 CASES

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO
EXCLUDE DR. SUZANNE PARISIAN, M.D.**

Plaintiffs respectfully submit this Memorandum of Law in Opposition to Defendants Ethicon, Inc. and Johnson & Johnson's ("Defendants") Motion to Exclude Dr. Suzanne Parisian, M.D.

Introduction and Qualifications of Dr. Suzanne Parisian

Dr. Parisian is medical doctor, pathologist, and regulatory expert who has served as regulatory and medical consultant since 1995. Dr. Parisian was an FDA employee. Dr. Parisian has over twenty-four years of experience in developing medical devices and began her career as a physician in 1980. Dr. Parisian served as a commissioned officer in the United States Public Health Service where she was assigned as a medical officer to the FDA's Center for Devices and Radiological Health ("CDRH"). During this period, Dr. Parisian's duties included both pre-market and post-market review and monitoring of issues related to medical devices. Def. Exhibit C. 6-7. Both in her position as an FDA employee and in her consulting business, Dr. Parisian reviewed hundreds of marketing applications and draft labeling for a conglomeration of medical devices. *Id* at 8. Additionally, she has been involved with product design and submissions for

approval or clearance to the FDA. In total, Dr. Parisian is eminently qualified to render her opinions because she has decades of experience working with pharmaceutical and medical devices.

Legal Standard

The task of evaluating the reliability of expert testimony is uniquely entrusted to the district court. *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 589 (1993). District courts enjoy “considerable leeway” in determining the admissibility of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Under Federal Rule of Evidence (“Rule”) 702 if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, provided the testimony (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” (3) which have been reliably applied “to the facts of the case.” See *Tyree*, 2014 WL 5320566 at *2; see also *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W.Va. 2013). A two part test governs the admissibility of expert testimony (and is combined with Rule 702’s qualification standard). See Rule 702; see also *Tyree*, 2014 WL 5320566 at *2. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597; see also *Tyree*, 2014 WL 5320566 at *2.

The proponent of expert testimony does not have the burden to “prove” anything. He must, however, “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998); *Tyree*, 2014 WL 5320566 at *2. All *Daubert* demands is that the trial judge serve as a gate keeper and make a “preliminary assessment” of whether the proffered

testimony is both reliable and helpful. *Tyree*, 2014 WL 5320566 at *3. In making the required preliminary assessment, the trial court “‘need not determine that the proffered expert testimony is irrefutable or certainly correct’” because, as with all testimony, it will be subject to “testing” by cross-examination, contrary evidence, and instruction on the burden of proof. See *Id.* (quoting *U.S. v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006)).

Legal Standard as Applied to Dr. Parisian

The testimony Dr. Parisian seeks to proffer is in full compliance with the standards set forth in Rule 702, Daubert and its progeny. See Rule 702; see also *Daubert*, 509 U.S. at 597 (to be admitted evidence must “rest [] on a reliable foundation and [be] relevant”); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) (“[T]he obligation of a district court to determine whether expert testimony is reliable and relevant applies to all expert testimony [i.e. scientific and non-scientific].”). In addition, Plaintiffs aver that applicable law requires that Rule 702 be applied flexibly, see *Daubert*, 509 U.S. at 594, so as to uphold the general framework of the Rules which favors the admissibility of evidence over non-admissibility. *Id.* at 588; see also *Tyree*, 2014 WL 5320566 at *3. In short, “the rejection of expert testimony is the exception rather than the rule.” *U.S. v. Stanley*, No. 12-4572, 2013 WL 3770713 at *1 (4th Cir. July 19, 2013) (internal quotations omitted in the cited quotation.). As such, Plaintiffs respectfully submit that the expert testimony proffered by Dr. Parisian should be admitted as set forth herein and that Ethicon’s Motion should be denied.

Argument

Rather than addressing the substance of Dr. Parisian’s opinions, Ethicon attempts to obfuscate the Court’s inquiry by presenting to the Court a hap hazard conglomeration of cases where Dr. Parisian’s opinions were limited, often only in part, to support sweeping and

generalized arguments to exclude Dr. Parisian's opinions. These opinions, involving different cases and different facts, have minimal relevance to the Court's inquiry *in this case*. In fact, Defendants conveniently fail to mention that Dr. Parisian has been allowed to testify in TVM state courts actions, and, in fact, proffered testimony in at least one TVM trial, *Barba v. Boston Scientific*. See Trial Trans. (5/18/2015) at 21:4-23:12; 26:11-98:17, attached as Ex. 1, *Barba v. Boston Scientific*, C.A. No. N11c-08-050 (Del. Sup. Ct.). In that matter, the Court found Dr. Parisian's opinions relevant and reliable to testify concerning the FDA regulatory process, the 510(k) clearance process, Boston Scientific's actions within that process, and Boston Scientific's labeling.

Defendants argue against opinions that Dr. Parisian does not offer, including opinions that Dr. Parisian overtly states she will not offer, in an attempt to conclude that Dr. Parisian has exceeded the bounds of her expertise. Not only does this create arguments that do not exist, but this strategy is blatantly flawed and should be summarily rejected by the Court. Indeed, Defendants' strategy of citing to cases involving different products where Dr. Parisian's opinions were limited is belied by its own acknowledgement that opinions on different products, not involving mesh, are irrelevant. See Def. Mot. at 11 (arguing that Dr. Parisian's opinions involving different products are irrelevant). Defendants fail to confront the reality of Dr. Parisian's report; that the only relevant inquiry before this Court is the reliability and relevance of Dr. Parisian's opinions on the Prolift+M and TVT-S, not the illusory opinions that Dr. Parisian does not offer or seek to present at trial.

I. Dr. Parisian Is Qualified To Offer The Opinions Set Forth In Her Report.

Defendants' motion is a classic straw man argument. Defendants argue at length against Dr. Parisian's qualifications to opine on medical causation issues and scientific testimony,

however, at no point do Defendants identify with any specificity, either in deposition testimony or in Dr. Parisian's expert report, which opinions extend into the realm of scientific testimony. Defendants premises this argument as one limited to Dr. Parisian's qualifications to testify as to scientific testimony, but shift and expand its conclusion to include subject matter well within Dr. Parisian's regulatory expertise including "product development, risks, design, testing, manufacturing, [and] studies." Def. Mot. at 9. Indeed, Dr. Parisian willingly admits that she does not intended to offer these opinions, a point tacitly acknowledged by Defendants. Def. Mot. at 5. Instead, the opinions that Dr. Parisian does offer are all well within her field of expertise; that of a regulatory expert. The Court should not be fooled by Defendants' slight of hand.

Defendants' argument center around their position that Dr. Parisian is unqualified to offer her opinions because "Dr. Parisian does not have sufficient qualifications to present this testimony, nor does she employ any methodology---let alone a reliable one. Although she is a licensed medical doctor and pathologist, **she has not treated a patient for nearly 30 years.**" Def. Mot. at 6. First, the fact that she has not recently treated patients is wholly irrelevant with respect to her qualifications, methodology, and opinions that she offers in these cases. When this Court was faced with similar criticisms of another regulatory expert by the Defendants in this MDL, it held that:

While it is true that Dr. Pence is not a doctor or biomedical engineer, she has more than forty years of experience in the research and development of pharmaceuticals and medical devices" and that when considering her additional role in presiding over a company that **"provides 'advice, guidance, and product development services to . . . medical device companies in the areas of strategic planning, preclinical testing, clinical trials design and conduct . . ."** that **"this experience is relevant to her opinion that Ethicon failed to act as a reasonably prudent manufacturer in testing the TVT, and she is therefore qualified to testify by her 'knowledge, skill, experience, training, or education[.]**" Fed. R. Evid. 702.

In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig., 2014 WL 186872, *30.

This Court has already considered, and rejected, the argument that specific, clinical expertise using a pelvic mesh device or practicing gynecology is an absolute prerequisite to offering an opinion on the labeling of such a device. *Id* at *29-32; *In re C.R. Bard, Inc.*, 948 F. Supp. 2d, at 627-631. Instead, that should go to the weight of her opinions at trial. Similar to other regulatory experts who have testified, Dr. Parisian has over twenty (20) years of experience in the drug and device regulatory field and over twenty-four (24) years of experience in the research and development of medical devices. Def. Ex. C at 6. Just as doctors Kessler and Pence were deemed qualified to offer expert regulatory opinions on the basis of their work for the FDA in this MDL, as well as the Bard and BSC MDLs, Dr. Parisian is qualified based on her similar experience and her opinions are admissible here.

Despite Dr. Parisian's clear qualifications to offer her opinions as a regulatory expert, Defendants attempt to recast the nature and foundation of her opinions. For example, Defendants highlight selected excerpts of Dr. Parisian's opinions to give the illusion that her opinions exceed her expertise. Defendants argue that Dr. Parisian attempts to opine on "safeguards... for conducting ethical research." Def. Mot. at 5. However, Dr. Parisian's opinion, as written in her Prolift+M report clearly states that "Ethicon has knowingly engaged in marketing of new investigational devices to United States Physicians ... without adherence to patient safeguards *such as occur in the FDA approved Investigational Device Exemption (IDE) for ethically collecting human data.*" Def. Ex. C at 35 (emphasis added). Not only does Dr. Parisian's extensive clinical experience qualify her to opine on regulatory issues, but the opinion she actually offers is considerably different from the opinion Defendants attribute to her report. This Court has previously held such opinions as to the appropriateness of premarket testing are admissible where a regulatory expert relies on studies and international standards. *See Mathison*

v. Boston Sci. Corp., No. 2:13-CV-05851, 2015 WL 2124991, at *15 (S.D.W. Va. May 6, 2015); *Sanchez v. Boston Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *34 (S.D.W. Va. Sept. 29, 2014), reconsideration denied, No. 2:12-CV-05762, 2014 WL 5320559 (S.D.W. Va. Oct. 17, 2014). Here, Dr. Parisian incorporates a multitude of international standards, including GHTF standards, NICE recommendations, and the HAS study. Def. Ex. C at 10; *Id* at p. 44. Fn. 38. Accordingly, the Court should not stray from its previous rulings and should deny Defendants' motion to exclude Dr. Parisian.

II. Defendants' Intent, Motive and "Narrative" Arguments Lack Merit.

Ethicon seeks to exclude Dr. Parisian's testimony, to the extent that it constitutes a narrative of documents or an expression of corporate intent. Def. Mem. at 9-12, 13-15. Plaintiffs will comply with this Court's prior rulings and will not elicit testimony from Dr. Parisian on Defendants' state of mind, motive, or intent. However, much of the testimony Defendants label as "state of mind" is merely a description of Ethicon's code of conduct, relevant industry standards, and Dr. Parisian's opinion that Ethicon failed to comply with these standards. These opinions do not necessarily delve into "state of mind" testimony that the Court has previously precluded, and are instead helpful to the jury by informing as to relevant industry and regulatory standards. Whether Ethicon failed to comply with its code of conduct or industry standards is not, as Ethicon asserts, knowledge or state of mind testimony but rather opinions as to industry standards which are in turn helpful to the jury. Similarly, whether, how, and when Ethicon communicated safety information to physicians and patients goes to the heart of Plaintiffs' failure to warn claims.

The opinions offered, are thus both relevant and helpful, as Dr. Parisian's expertise on regulatory and industry standards aids the jury in determining whether Defendants breached their

code of conduct. Moreover, this Court rejected a similar argument that Ethicon advanced in *Lewis* with respect to “narrative” testimony. 2014 WL 186872, at *21. In *Lewis*, Ethicon argued that Dr. Bruce Rosenzweig’s testimony was inadmissible because “much of Dr. Rosenzweig’s expert report is a summary of company documents, exhibits, and websites.” *Id.* This Court rejected that argument, ruling that reliance on those materials “is helpful to the jury [in] understand[ing] the plaintiffs’ . . . claims.” Similarly, in *Cisson v. C.R. Bard, Inc.*, this Court allowed an expert to offer factual narrative testimony “to the extent that [the narratives] may present the bases for the[] expert opinions.” 948 F. Supp. 2d 589, 646 (S.D.W. Va. 2013). Likewise, the court in *Smith v. Pfizer* rejected this exact argument, holding “[Plaintiff’s expert] may properly testify as to his interpretation of internal marketing-related documents that he relied on in forming his opinions.” 714 F. Supp. 2d 845, 857 (M.D. Tenn. 2010). The same result is warranted here. For these reasons, the Court should deny Defendants’ motion.

Dr. Parisian’s proffered testimony is not an impermissible narrative, but rather proper testimony for the jury that is precisely within her realm of expertise. Other courts have determined that an expert may properly testify about, or comment upon, any document or exhibits in evidence, and may explain “the regulatory context in which they were created, defining any complex or specialized terminology or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge.” *In re Fosamax*, 645 F.Supp.2d at 192. Thus, the factual materials considered by Dr. Parisian are not intended to be the subject of her testimony in and of themselves. Rather, the documents, evidence and factual matters referenced form the basis of her opinion and are relevant and helpful to the jury in explaining the regulatory context in which they were created. This testimony illustrates the considerations that are relevant at different stages of the regulatory process, and allows Dr.

Parisian to apply her expertise to draw inferences that would not otherwise be apparent to the jury. The use of factual materials in this way does not violate the rule against factual narratives. *Id.*

Further, Plaintiffs disagree with the characterization of Dr. Parisian's testimony as a factual narrative because the "appropriate solution" is not to "parse the expert's report;" but, rather, to trust that plaintiffs' counsel will only present the facts necessary to the expert's opinion and that the Court will be able to cut off lengthy factual narratives (if any) at trial. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d, at 645-646. Thus, if Defendants truly believe that there is a lack of connection between the facts and Dr. Parisian's expert opinions, the better time to object to narrative testimony is at trial. *Staub v. Breg, Inc.*, 2012 WL 1078335 *3 (D. Ariz. 2012).

III. Dr. Parisian's Opinion That Ethicon Failed To Comply With Applicable Post Market Vigilance Standards Is Admissible.

Medical device manufacturers have an obligation to ensure that their labeling is and remains adequate over the course of the lifecycle of its products. This is the heart of a failure to warn claim. As the product was introduced and remained on the market, a central question is whether Ethicon's Instructions for Use ("IFU") adequately informed physicians of known or knowable safety risks so both surgeons and patients could make informed decisions. Federal Regulations require medical device companies to report and analyze safety information as it is received while a product remains on the market. *See e.g.*, 21 C.F.R. § 803.50(a). For the reasons more fully stated below, Defendants' arguments confuse the nature and scope of the opinions offered by Dr. Parisian with respect to adverse event reporting or other data regarding the safety profile of the Prolift+M and TVT-S devices, and should therefore be denied.

For example, Defendants' argument to exclude Dr. Parisian's opinions on post-market

vigilance is misplaced. Ethicon attempts to characterize this testimony as strictly whether, how, and when Ethicon communicated safety information to the FDA. Such testimony is admittedly irrelevant and will not be offered at trial. However, whether, how and when Ethicon communicated safety information to physicians and patients goes to the heart of Plaintiffs' failure to warn claims and is therefore admissible.

IV. Dr. Parisian Is Qualified To Opine Upon Foreign Regulatory Matters And This Testimony Will Be Helpful To The Jury.

Ethicon argues that Dr. Parisian is not qualified to opine on foreign regulatory matters because she has only a “‘working familiarity’ with ‘international standards and requirements’”. Def. Mot. at 15. However, Dr. Parisian explains in detail her unique qualifications to opine on foreign regulatory matters, including practical application of global industry standards. Def. Ex. C at 18. These experiences include presentations to foreign medical associations as well “helping regulated industry obtain acceptance and reimbursement by foreign regulatory agencies.” *Id.* Not only, does Dr. Parisian have practical working experience in this field, but she provides a detailed explanation of her methodology on this point. *Id.* Although she may not be qualified to opine on the “laws” of foreign counties, her report and testimony indicate that her opinions do not delve into such matters, but are instead limited to global *regulatory standards*, to which she is qualified. Dr. Parisian’s considerable experience renders her qualified to offer these opinions.

Dr. Parisian’s opinions on international regulatory standards are similarly helpful to the jury. This court has previously held that opinions on such standards are admissible. *See Mathison v. Boston Sci. Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *15 (S.D.W. Va. May 6, 2015) (“GHTF standards, on the other hand, do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. And although the FDA appears to have had a limited role in the activities of the GHTF that

role was not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA.”) (internal citations omitted). Further, the Court found that such reliance on international standards was both reliable and helpful to the jury where a regulatory expert opined on such matters as premarket testing and some product labeling matters. *Id* at *15. Because Dr. Parisian’s reliance on international standards is both reliable and helpful, her opinions should not be excluded *per se* simply because she incorporates international standards within her methodology.

V. Dr. Parisian Is Qualified To Opine On Warnings For Either The Prolift+M or TVT-S.

Next Defendants attack Dr. Parisian’s qualifications to testify and opine upon warnings, first arguing that other Courts have excluded her testimony in unrelated cases and secondly that Dr. Parisian lacks the experience and qualifications to form her opinions. Defendants’ first argument is meritless and the second argument incorrect. *See e.g., Keffer v. Wyeth*, 791 F. Supp. 2d 539, 545 (S.D.W. Va. 2011) (denying summary judgment on the basis of Dr. Parisian’s testimony as to warnings). These arguments are nearly identical for both the Prolift+M and TVT-S and Plaintiffs will address Defendants’ criticisms of Dr. Parisian’s qualifications together for the sake of brevity. Defendants’ criticism of Dr. Parisian’s qualifications centers almost exclusively on her lack of involvement with the specific devices at issue, either drafting patient brochures or IFUs for the devices at issue, or treating patients. Def. Mot. at 16, 22. These objections are unavailing as this Court has previously held that treatment of patients is not a prerequisite for Daubert admissibility. *See In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2014 WL 186872, *30. Here, although Dr. Parisian has not drafted an IFU for the Prolift+M, Ethicon’s assertion that Dr. Parisian “has never drafted an IFU or patient brochure that she believes is adequate” is patently false as her testimony demonstrates:

Q. Did you help create an IFU?

A. For the investigators, yes, sir.

Def. Ex. E; Deposition of Dr. Suzanne Parisian, March 8, 2016 at 54:2-3.

Similarly, Dr. Parisian has experience with patient brochures:

Q. Have you ever drafted a patient brochure for a surgically implantable device?

A. At the FDA I commented on them in terms of surgically implantable devices. I have not drafted it from square on. But in terms of medical devices, you're often more interactive with companies in terms of – like, I know I was involved with implantable cardiac defibrillators when they first came out and also some of the – so those would have been issues that I was looking at the labels, but I didn't draft them.

Def. Ex. E at 56:5-15.

Thus, Defendants' argument is predicated on the assumption that an expert must have been directly involved in drafting IFU's or patient brochures for the *exact device* at issue in order to pass *Daubert*. Such an assumption has no support in the law and this Court has previously found regulatory experts *qualified* to render similar testimony in the absence of direct involvement with product specific IFUs and patient brochures. *See Winebarger* 2015 WL 1887222, at *18 (finding regulatory expert qualified to testify on opinions offered in expert report which included IFUs and patient brochures).¹ Rather, the fact that she has not drafted an IFU for these specific devices goes towards the weight of her testimony at trial, not the admissibility. Further, as set forth above, Dr. Parisian testified in the *Barba* trial with respect to Boston Scientific's IFU's, even though she had never crafted an IFU for the two devices at issue in that case. Ex. 1, Trial Trans. (5/18/2015) at 21:4-23:12; 26:11-98:17. Dr. Parisian's extensive

¹ The Court did exclude some of Dr. Pence's opinions as unreliable, however no opinions were excluded on the basis of qualification. *Winebarger*, 2015 WL 1887222, at *20

experience drafting or commenting upon IFU's and patient brochures renders her sufficiently qualified to testify as to her opinions.

Defendants next attempt to discredit Dr. Parisian's qualifications by misconstruing her testimony. Defendants argue that Dr. Parisian could not recall whether she had seen the Prolift+M patient brochure, however the deposition testimony Defendants cite to concerns the Prolift+M surgeon's resource monograph and the patient brochure which Dr. Parisian acknowledged "looked familiar." Def. Ex. E at 88:25-89:8; 161;13-162:4. Moreover, Defendants take Dr. Parisian's testimony out of context and fail to inform the Court that Dr. Parisian reviewed several version of patient brochures in forming her opinion and drafting her report:

Q. As I understand it, there have been several versions of various patient brochures that you've reviewed; correct?

A. Yes, sir.

Def. Ex. E at 160:4-7

Thus, Dr. Parisian's inability to recall a particular patient brochure is not evidence that she did not review *any* of Ethicon's patient brochures. And, again, this argument should go to the weight of her testimony at trial, not its admissibility.

Similarly, Dr. Parisian's failure to speak with physicians who implanted the Prolift+M device or TVT-S is insufficient to show that she is unqualified to testify on the issue of warnings and labels. Ethicon argues that failing to speak with physicians or surgeon renders her unqualified to opine on warnings, however such a shortcoming is not grounds for exclusion. Def. Mot at 17. This Court has previously held that "[a]n expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert*, so long as the expert has other 'sufficient facts or data' to support her opinion. Fed.R.Evid. 702; *Mathison v. Boston Sci. Corp.*,

No. 2:13-CV-05851, 2015 WL 2124991, at *18 (S.D.W. Va. May 6, 2015). Here, Dr. Parisian's opinions are predicated on sufficient facts and data to render her opinions reliable and the criticisms offered by Ethicon are better reserved for cross examination at trial. *Id.*

VI. Dr. Parisian Employs a Reliable Methodology to Form Her Opinions On Prolift+M and TVT-S Warnings.

Defendants' criticism of Dr. Parisian's methodology centers upon a perceived lack of knowledge of non-mesh procedures. Def. Mot. at 18 ("Dr. Parisian also admitted at her deposition that she does not know the risks of non-mesh pelvic organ prolapse surgeries"). However, much of Defendants' argument on this point is irrelevant to the actual opinions offered in Dr. Parisian's report, as Defendants simply group all of Dr. Parisian's "warnings" opinions together. For example, Dr. Parisian's opinions that "Ethicon did not voluntarily update and timely circulate Prolift/Prolift+M labels to physicians which fully notified them of changes requested by the FDA" (opinion #7 on Prolift+M) and that "Ethicon continued to market Prolift with an inaccurate and misleading label when it did not implement and circulate or notify surgeons about changes in the cleared final label until after 2009" (opinion #8 on Prolift+M) are opinions centered upon industry standards and regulatory norms. These opinions have little to do with patient specific medical determinations but everything to do with regulatory matters, how Ethicon communicated with physicians, and industry standards, opinions Dr. Parisian is qualified to provide.²

Similarly, Defendants often confuse Dr. Parisian's opinions. For example, Dr. Parisian offers the opinion that "Ethicon marketed to Prolift with an *inaccurate* and *misleading* label"; however, Defendants confuse this opinion with one as to the *adequacy* of the product label. *Compare* Def. Ex. C at 82; Def. Mot. at 20. Dr. Parisian forms this opinion through employment

² For example, Dr. Parisian notes that Ethicon included data for the Prolift within its Prolift+M label implying that there was data available for the Prolift+M when there was none. See Def. Ex. C at ¶¶ 224-225.

of global industry standards and review of FDA and Ethicon documents. Def. Ex. C at 14, 15. A cursory review of Dr. Parisian's opinion that the Prolift was marketed with inaccurate and misleading labeling reveals that Dr. Parisian arrived at this conclusion by examining what the FDA requested of Ethicon, Ethicon's actions, and the data available to Ethicon that informed its actions. Def. Ex. C at 82. This opinion, and other similar opinions offered by Dr. Parisian, do not require specialized knowledge of surgical procedures, knowledge of the risks of non-mesh procedures or complications, all factors Defendants consider relevant in arguing that Dr. Parisian fails to employ a reliable methodology. Instead, Dr. Parisian's opinions revolve around regulatory expertise and industry standards. Because Dr. Parisian's opinion here centers upon the accuracy of the product label, Defendants' arguments related to adequacy of the methodology are misplaced and irrelevant.

CONCLUSION

For the above reasons, Dr. Parisian is qualified to render the opinions she is called to make and those opinions are relevant and based on reliable methodology and will assist the jury. Consequently, her opinions are admissible and Defendants' Motion should be denied in full.

Dated: May 9, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, a true and correct copy of this Response, and exhibits, was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Aimee H. Wagstaff, Esq.